

REMARKS

The Final Office action dated May 11, 2009 is acknowledged. Claims 1-90 are pending in the instant application. According to the Office action, claims 1-6, 11-23, 42-46 and 83-90 are rejected and claims 7-10, 24-41 and 47-82 have been withdrawn. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 1-6, 11-23, 42-46 and 83-90 under 35 U.S.C. 103(a)

Claims 1-6, 11-23, 42-46 and 83-90 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2001/0006677 (McGinity, et al.) in view of U.S. Patent No. 6,177,096 (Zerbe, et al.). The Examiner argues that McGinity, et al. teach effervescent polymeric film drug delivery systems that are adapted for direct oral or buccal administration and that the formulations provide for a rapid rate of release of an active ingredient that ranges from immediate to a period of about 10 minutes. The Examiner continues on in the Final Office action to argue that the reference teaches every limitation of the presently claimed invention, except for the limitation that the coating compound composition is dried.

The Examiner in turn refers to Zerbe, et al. for teaching water soluble film for oral administration with instant wettability, and for teaching any of the missing limitations of McGinity, et al. except for the limitation of at least one or two gas forming agents. However, in this regard, the Examiner states that when using a non-aqueous solvent in the process for making the compositions of McGinity, et al., it would have been obvious to have dried the film to remove the solvent with the motivation to form a dry film, as

disclosed by Zerbe, et al. The Examiner also concludes that it would have been obvious to use a non aqueous solvent to dissolve the components of the film composition, cast the films and dry them to make the compositions of McGinity, et al. motivated by the desire to avoid high temperatures that may degrade the effervescent components by using a method disclosed in the art that is used to make water dispersible films with a compatible solvent.

Regarding claims 84 and 88, the Examiner states that it is generally *prima facie* obvious to select a known material for incorporation into a composition based on its recognized suitability for its intended use. Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to have used an acrylate polymer in the composition of McGinity, et al. motivated by the desire to use a water-dispersible polyacrylate for its function as a binding agent in a water dispersible film.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider Block, et al. alone, or in combination with the cited secondary references, each and every limitation of the present

invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully disagree with the Examiner's conclusion set forth in the Final Office action. It is respectfully submitted that the Examiner has applied an incorrect meaning to the terms "suspending agent" and "non-aqueous solvents" when interpreting the disclosure of the McGinity, et al. reference. The Applicants submit that, generally, suspensions and solutions are understood in the art to be in the liquid state (see Exhibit A – copies from Webster's online dictionary defining "solvent" and "suspension"). On page 4 of the Office action, the Examiner alleged that the substances mentioned in paragraph [0094] would act as suspending agents.

According to the Examiner, in the Office action at page 4, line 2, McGinity, et al. teach that "the components are mixed together" and that this would be equivalent to suspending the components in a suspending agent. However, the Applicants submit that this interpretation is inappropriate. A mixture is not equivalent to a solution or a suspension. For example, the enclosed Wikipedia page (Exhibit B) provides that a mixture is when two or more different substances are mixed together but not combined chemically, while a suspension is when the particles of one substance are suspended in the other substance. The Examiner referred to paragraphs [0082] and [0094] which, however, refer to a mixture of solids. Contrary to the Examiner's opinion, the substances mentioned in paragraph [0082] would never be regarded as "non-aqueous solvents" by one skilled in the art.

Furthermore, present claim 1 requires that the coating compound is dried (see the

last process step). Drying, in general, refers to the removal of volatile liquid components (Exhibit C –

http://www.google.com/search?hl=en&defl=en&q=define:Drying&ei=Kx eoSumGCISC MqbR0JIC&sa=X&oi=glossary_definition&ct=title). In a process by which a film is produced by coating a coating compound and subsequent drying, the drying process serves to remove the (liquid) solvents or dispersing agents that were used for preparing the coating compound (see also Zerbe, et al. ('96 patent), Col. 1, lines 31-34: "drying ... to remove the solvents completely"). The Applicants thus submit that it would be quite apparent to one skilled in the art that the substances disclosed in paragraph [0082] of McGinity, et al. cannot be removed by drying.

In this regard, the Examiner states (in the Office action at page 4, lines 10-11) that the McGinity, et al. reference differs from the instant claims insofar as the reference does not disclose that the coating compound is dried. However, this follows directly from the fact that the coating compositions described by McGinity, et al. do not contain any solvents or dispersing agents that could be removed by drying.

In view of the above, the Applicants contest the Examiner's position that McGinity, et al. teach a step of suspending (or dissolving) the components in a non-aqueous suspending agent (or solvent).

In turn, the Applicants submit that since McGinity, et al. fail to disclose using a non-aqueous solvent in the process of making the compositions, the Examiner's conclusion (page 5, lines 8-10 of the Office action) stating that it would have been obvious to have dried the film to remove the solvent motivated by the desire to form a dry

film is unfounded. The citations clearly support the Applicants' latter submission disagreeing with the Examiner's conclusion.

The Applicants also submit that the Examiner's argument is inconsistent in consideration of the conclusion recited in the Office action (page 5, lines 11-15) that it "would have been obvious to use a non-aqueous solvent to dissolve the components of the film composition ... motivated by the desire to avoid high temperatures that may degrade the effervescent components." This appears to be contrary to the passage on page 4, lines 4-5 of the Office action, where the Examiner states that the compositions of McGinity, et al. may comprise non-aqueous solvents (which is contested). From the above-quoted passage (page 5, lines 11-15), it appears that the Examiner is no longer sure whether McGinity, et al. teach non-aqueous solvents. Moreover, the Examiner has not indicated any reason why the effervescent components may be degraded by high temperatures. McGinity, et al. do not teach that the effervescent components are susceptible to degradation by heat.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims are not set forth in the McGinity, et al., alone or in combination with the cited secondary reference. In addition, Zerbe, et al. fail to make up for any of the missing limitations of McGinity, et al. Moreover, one skilled in the art would not be motivated to combine said references or to modify McGinity, et al. to arrive at the presently claimed invention. Therefore, the

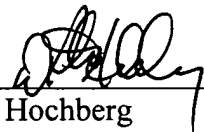
Applicants respectfully request that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: September 10, 2009

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Solvent

Definition: Solvent

Solvent

Adjective

1. Capable of meeting financial obligations.

Noun

1. A liquid substance capable of dissolving other substances; "the solvent does not change its state in forming a solution".
2. A statement that solves a problem or explains how to solve the problem; "they were trying to find a peaceful solution"; "the answers were in the back of the book"; "he computed the result to four decimal places".

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Date "solvent" was first used in popular English literature: sometime before 1822. ([references](#))

Specialty Definition: Solvent

Domain	Definition
Archeological	A substance capable of dissolving another substance. Solvents are often liquids and tend to be volatile. Different solvents are needed for dissolving different substances, depending on chemical composition. A common solvent is acetone. (references)
Chemical Industry	Any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff. Source: European Union. (references)
Finance	Capable of fulfilling one's financial obligations. Source: European Union. (references) The state of being able to meet expenses and pay debts. (references)
Health	1. dissolving; effecting a solution. 2. a liquid that dissolves or that is capable of dissolving; the component of a solution that is present in greater amount. (references) A liquid capable of dissolving or dispersing another substance (for example, acetone or mineral spirits). (references)
Hydrologic	A substance that dissolves other substances, thus forming a solution. Water dissolves more substances than any other, and is known as the "universal solvent". (references)
Mining	A. A substance used to dissolve another substance b. That component of a solution that is present in excess; or the physical state of which is the same as that of the solution. (references)

Source: compiled by [the editor](#) from various references; see credits.

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Synonyms: Solvent

Synonyms: answer (n), dissolvent (n), dissolver (n), dissolving agent (n), resolution (n), resolvent (n), result (n), solution (n). ([additional references](#))

Synonym by domain: dissolver (mechanical engineering, physics).

Antonym: insolvent (adj). ([additional references](#))

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Synonyms within Context: Solvent

Context	Synonyms within Context (source: adapted from Roget's Thesaurus).
Decomposition	Adjective: decomposed; Verb: catalytic, analytical; resolvent, separative, solvent.
Liquefaction	Solvent, menstruum, alkahest.
Wealth	Flush, flush of cash, flush of money, flush of tin; in funds, in cash, in full feather; solvent, pecunious, out of debt, in the black, all straight.

Source: adapted from [Roget's Thesaurus](#).

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Crosswords: Solvent

English words defined with "solvent": acetamide, acetone, acetum, alkahest, alkahest, amyl alcohol • butanone • Camphene, carbon disulfide, carbon tetrachloride, concentrate • dimethyl ketone, Dissolutive, dissolvent, dissolver, dissolving agent, dry cleaning, Dry distillation • elute, elution, Etching figures, ethanal trimer, ethanamide, ethanediol, ethanol, ethyl acetate, ethyl alcohol, ethylene glycol • fermentation alcohol, ferrite, fufural, fufuraldehyde • garnet lac, gastric digestion, glycol, grain alcohol • heat of solution, heptane, hexane • isopropanol, isopropyl alcohol • Laky, Ligroin, Lixivation • m. Menstruum, methanol, methyl alcohol, methyl ethyl ketone, methylbenzene, methylene chloride, molar, molar, molar concentration, molarity • nitrobenzene, Nitrohydrochloric acid, Nonsolvent • octane, oil of turpentine, osmotic pressure • paraldehyde, perchloromethane, pervaporation, propanol, propanone, propyl alcohol • remover, resolvent, rubber cement • Salt of sorrel, solubility, soluble, Solvability, solvate, solvation, spirit of turpentine • tetrachloromethane, toluene, turpentine, turps • universal solvent, unsuitable • wood alcohol, wood spirit • xylenes, xylol. ([references](#))

Specialty definitions using "solvent": Chlorinated Solvent • EXTRACTOR OPERATOR, SOLVENT PROCESS • nonpolar solvent • Oxygenated Solvent • pregnant solvent • solvent extraction. ([references](#))



Webster's Online Dictionary with Multilingual Thesaurus Translation			
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<input type="radio"/> English		<input type="radio"/> Non-English	

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Suspension

Definition: Suspension

Suspension

Noun

-
1. A mixture in which fine particles are suspended in a fluid where they are supported by buoyancy.
 2. A time interval during which there is a temporary cessation of something.
 3. Temporary cessation or suspension.
 4. An interruption in the intensity or amount of something.
 5. A mechanical system of springs or shock absorbers connecting the wheels and axles to the chassis of a wheeled vehicle.
 6. The act of suspending something (hanging it from above so it moves freely); "there was a small ceremony for the hanging of the portrait".
 7. A temporary debarment (from a privilege or position etc).

Source: [WordNet 1.7.1](#) Copyright © 2001 by Princeton University. All rights reserved.

Date "suspension" was first used in popular English literature: sometime before 1615. ([references](#))

Etymology: Suspension \Sus*pen"sion\, noun. [Compare to the French expression suspension, from Latin expression suspensio arched work, imperfect pronunciation. See Suspend.]. ([references](#))

Specialty Definition: Suspension

Domain	Definition
<u>Computing</u>	Suspension In lazy evaluation, a suspension (or in Henderson's terminology, a "recipe") is a closure with a flag indicating whether the expression has been evaluated or not. When the expression is evaluated the first time, this flag is set. Subsequent requests for the value of the expression will not attempt to re-evaluate it. (1995-02-06). Source: The Free On-line Dictionary of Computing .
<u>Aerospace</u>	In physical chemistry, a system composed of one substance (suspended phase, suspensoid) dispersed throughout another substance (suspending phase) in a moderately finely divided state, but not so finely divided as to acquire the stability of a colloidal system. Given sufficient time, a suspension will, by definition, separate itself by gravitational action into two visibly distinct portions, whereas a colloidal system, by definition, is stable. Dust in the atmosphere is an example of a suspension of a solid in a gas. (references)
<u>Agriculture</u>	A process under the Federal Insecticide, Fungicide, and Rodenticide Act by which the Environmental Protection Agency can suspend the use of a pesticide in order to prevent an imminent hazard resulting from its continued use. An emergency suspension takes effect immediately; under an ordinary suspension a registrant can request a hearing before the suspension goes into effect. Such a hearing process might take several months. (references)

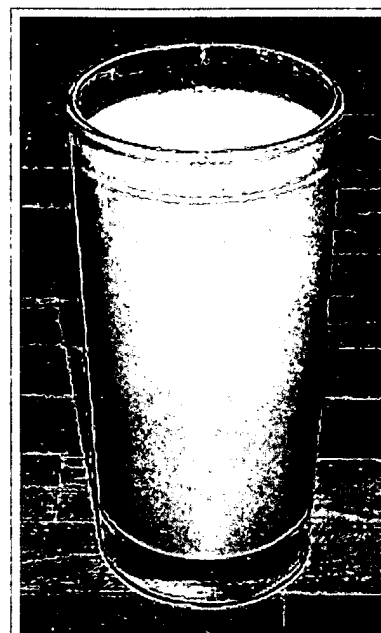
Mixture

From Wikipedia, the free encyclopedia

In chemistry, a **mixture** is when two or more different substances are mixed together but not combined chemically. The molecules of two or more different substances are mixed in the form of solutions, suspensions, and colloids.

While there are no chemical changes to its constituents the physical properties of a mixture, such as its melting point, may differ from those of the components. Some mixtures can be separated into their components by mechanical means. Mixtures are either homogeneous or heterogeneous.

Mixtures are the product of a blending (<http://en.wiktionary.org/wiki/blend|mechanical>) or mixing of chemical substances like elements and compounds, without chemical bonding or other chemical change, so that each ingredient substance retains its own chemical properties and makeup.^[1]



A suspension of flour in water, a heterogeneous mixture

Contents

- 1 Suspensions
- 2 Colloidal dispersions
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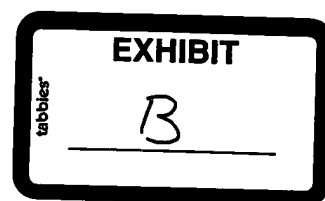
Suspensions

Main article: Suspension (chemistry)

A heterogeneous mixture is one with uneven distribution within the mixture (due to phases or particle size). A suspension is when the particles of one substance are suspended in the other substance (the two substances do not mix into a 'seam-less' mixture- a 'whole'). An example of a suspension is putting flour in water. You can see the water as a separate substance from the particles of flour (the flour is obviously not blended with the water). A Mixture can be reversed unlike a chemical reaction.

Colloidal dispersions

Main article: Colloid



Colloids are mixtures in which the particles of one or more components have at least one dimension in the range of 1 to 10 nm, larger than those in a solution but smaller than those in a suspension. Colloids are the same as suspensions, except they don't leave sediments.^[2] In general, a colloid or colloidal dispersion is a substance with components of one or two phases. It creates the Tyndall effect when light passes through it. A colloid will not settle. Jelly, milk, blood, paint, fog, shampoo, and glue are examples of colloid dispersions.

Mixtures and compounds

A compound is not a mixture. A compound has very different properties than the elements it is made of, but a mixture contains several substances which keep their properties.

References

- ↑ Atkins' Physical Chemistry, 7th Ed. by Julio De Paula, P.W. Atkins ISBN 0198792859
- ↑ Chemistry: Matter and its Changes, 4th Ed. by Brady, Senese, ISBN 0471215171

International Union of Pure and Applied Chemistry. "mixture (<http://goldbook.iupac.org/M03949.html>) ". *Compendium of Chemical Terminology* Internet edition.

See also

- Solution

Retrieved from "<http://en.wikipedia.org/wiki/Mixture>"

Categories: Chemical mixtures

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Definitions of Drying on the Web:

- Drying of Bioproducts is a mass transfer process resulting in the removal of water moisture or moisture from another solvent, by evaporation from a solid, semi-solid or liquid (hereafter product) to end in a solid state. ...
en.wikipedia.org/wiki/Drying
- Drying is a method of food preservation that works by removing water from the food, which prevents the growth of microorganisms and decay. ...
[en.wikipedia.org/wiki/Drying_\(food\)](http://en.wikipedia.org/wiki/Drying_(food))
- dry - free from liquid or moisture; lacking natural or normal moisture or depleted of water; or no longer wet; "dry land"; "dry clothes"; "a dry climate ...
- dry - humorously sarcastic or mocking; "dry humor"; "an ironic remark often conveys an intended meaning obliquely"; "an ironic novel"; "an ironical smile"; "with a wry Scottish wit"
- dry - lacking moisture or volatile components; "dry paint"
- dry - opposed to or prohibiting the production and sale of alcoholic beverages; "the dry vote led by preachers and bootleggers"; "a dry state"
- dry - not producing milk; "a dry cow"
- dry - (of liquor) having a low residual sugar content because of decomposition of sugar during fermentation; "a dry white burgundy"; "a dry Bordeaux"
- dry - without a mucous or watery discharge; "a dry cough"; "that rare thing in the wintertime; a small child with a dry nose"
- dry - not shedding tears; "dry sobs"; "with dry eyes"
- dry - lacking interest or stimulation; dull and lifeless; "a dry book"; "a dry lecture filled with trivial details"; "dull and juiceless as only book knowledge can be when it is unrelated to...life"- John Mason Brown
- dry - used of solid substances in contrast with liquid ones; "dry weight"
- dry - unproductive especially of the expected results; "a dry run"; "a mind dry of new ideas"
- dry - having no adornment or coloration; "dry facts"; "rattled off the facts in a dry mechanical manner"
- dry - (of food) eaten without a spread or sauce or other garnish; "dry toast"; "dry meat"
wordnetweb.princeton.edu/perl/webwn

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